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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/564,401	01/11/2006	Yi Yan Yang	6565-73089-01	1799
24197 7590 01/27/2010 KLARQUIST SPARKMAN, LLP 121 SW SALMON STREET SUITE 1600 PORTLAND, OR 97204				
EXAMINER				
GULLEDGE, BRIAN M				
ART UNIT		PAPER NUMBER		
1612				
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/564,401

**Applicant(s)**

YANG ET AL.

**Examiner**

Brian Guldge

**Art Unit**

1612

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 October 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1 and 3-45 is/are pending in the application.
- 4a) Of the above claim(s) 21-45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/GS-06)  
Paper No(s)/Mail Date 6/10/09, 8/26/09, 10/27/09
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Previous Rejections***

Applicants' arguments, filed 27 October 2009, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

### ***Information Disclosure Statement***

The information disclosure statement filed June 10, 2009 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because it lacks either a statement as specified in 37 CFR 1.97(e) or it lacks the fee set forth in 37 CFR 1.17(p). It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a).

### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

**Claims 1 and 3-13 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Gan et al. (*Polymer*, 1997, 38(21), pages 5339-5345) in view of Vakkalanka et al. (*Polymer Bulletin*, 1996, 36, pages 221-225).** Applicant argues that the rejection is not proper. Applicant argues that Vakkalanka et al. teaches away from the claimed invention. The claims recite a process for preparing a thermosensitive polymer, the process involving combining the monomers to be used, and then polymerizing the monomers together. The product formed thus should be a random copolymer. The Applicant argues that Vakkalanka et al. teaches incorporating the *N*-isopropylacrylamide into polymers as a block of pre-polymerized *N*-isopropylacrylamide monomers, and teaches that this affords significant temperature sensitivity (page 221, first paragraph). Vakkalanka et al. teaches that if the *N*-isopropylacrylamide is incorporated as a random copolymer, the *N*-isopropylacrylamide content of the polymer needs to be significant to show temperature sensitivity (page 221, last partial paragraph). As such, one of ordinary skill in the art would not incorporate *N*-isopropylacrylamide into the polymer taught by Gan et al. as a random copolymer (as instantly recited) but rather as a block copolymer, and thus the claims as not rendered obvious in view of the teachings of Vakkalanka et al.

The Examiner is not persuaded by these arguments. The Examiner agrees with the statements summarizing Vakkalanka et al., in that by using a polymeric block of *N*-isopropylacrylamide instead of a random copolymer with the *N*-isopropylacrylamide, Vakkalanka et al. teaches less *N*-isopropylacrylamide needs to be incorporated into the polymer to have significant temperature sensitivity. However, this is not considered to teach away from the use of a random copolymer. Both methods of incorporation are taught by Vakkalanka et al. to be useful. If one of ordinary skill in the art desired to use less *N*-isopropylacrylamide in the

polymer, a block would allow for less to be used while retaining temperature sensitivity. However, this requires the pre-polymerization of a block of *N*-isopropylacrylamide polymer, then an additional polymerization step to incorporate the block into the copolymer (page 222, first full paragraph). In other words, there is a sacrifice in time (an additional step) in order to use less *N*-isopropylacrylamide. The Examiner does not consider Vakkalanka et al. to teach away from random copolymers, but rather teach an alternative for how one of ordinary skill in the art could use less monomer to have the desired effect. Even if the block copolymer was preferred, disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or non-preferred embodiments. See MPEP 2123.

**Claims 14-20 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Gan et al. (*Polymer*, 1997, 38(21), pages 5339-5345) and Vakkalanka et al. (*Polymer Bulletin*, 1996, 36, pages 221-225) as applied to claim 13 above, and further in view of Liu et al. (*Langmuir*, 1997, 13(24), pages 6421-6426).** The Applicant argues that the rejection is not proper because Liu et al. does not compensate for the defect in the combination of Gan et al. and Vakkalanka et al. discussed above. The Applicant also argues that the amounts instantly recited are not obvious in view of the references, as the precise amounts recited are not taught, and there is no teaching in the references to direct the skilled artisan to the precise amounts and proportions that are claimed.

The Examiner is not persuaded by these arguments. First, the Examiner is not persuaded that Liu et al. needs to compensate for a defect in the combination of Gan et al. and Vakkalanka et al., as discussed with regards to the rejection of instant claims 1-13 over those two references.

As for the amounts, the references do not teach the precise amounts that are claimed. However, the ranges taught for the amounts to use for some of the ingredients overlap the recited amounts, and in cases involving overlapping ranges, the courts have consistently held that even a slight overlap in range establishes a *prima facie* case of obviousness. *In re Peterson*, 65 USPQ2d 1379, 1382 (Fed. Cir. 2003). And as for the remaining ingredients, Liu et al. taught that the amounts of the 2-hydroxyethyl methacrylate,  $\omega$ -methoxy poly(ethylene oxide)<sub>40</sub> undecyl- $\alpha$ -methacrylate, and water can be varied to control the pore size of the material, and it would have been *prima facie* obvious for the skill artisan to optimize these result-effective variables, as stated previously.

**Claims 1 and 3-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gan et al. (*Polymer*, 1997, 38(21), pages 5339-5345) in view of Lee et al. (*J. Appl. Polymer Sci.*, 1999, 71, pages 221-231).** Gan et al. discloses the formation of microstructured materials with pore sizes in the nanometer range using the polymerizable surfactant  $\omega$ -methoxy poly(ethylene oxide)<sub>40</sub> undecyl- $\alpha$ -methacrylate, in microemulsions containing methyl methacrylate and 2-hydroxyethyl methacrylate (page 5339, third paragraph) as well as water and the cross-linker ethylene glycol dimethacrylate (page 5342, second full paragraph). Gan et al. further discloses the inclusion of the photo-initiator 2,2-dimethoxy-2-phenylacetophenone in the microemulsions (page 5341, table 1). The microemulsion was placed in a photochemical reactor chamber to polymerize (last paragraph starting on page 5340). Gan et al. does not teach the further inclusion of *N*-isopropylacrylamide.

Lee et al. teaches the preparation of hydrogels from the polymerization of *N*-isopropylacrylamide, acrylamide, and 2-hydroxyethyl methacrylate (abstract, lines 1-3). Lee et

al. teaches that copolymers of *N*-isopropylacrylamide are sensitive to temperature (page 221, second paragraph, lines 12-18), and *N*-isopropylacrylamide is a monomer that forms a thermosensitive polymer according to the applicant's definition (paragraph [29], lines 5-7). Lee et al. teaches incorporating the *N*-isopropylacrylamide into the polymer by copolymerizing all of the monomers together in solution (page 222, section entitled "Preparation of Hydrogels").

Lee discloses that the temperature-sensitive character of the polymer is influenced mainly by the amount of *N*-isopropylacrylamide present (page 225, second full paragraph). One practical use disclosed by Lee et al. for controlling temperature selectivity is the release of small molecules from the polymeric matrix, such as drugs (page 230, first full paragraph), and that by varying the amount of *N*-isopropylacrylamide present, the amount and rate of release of the drug (page 230, second full paragraph).

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have incorporated *N*-isopropylacrylamide into the polymeric material taught by Gan et al., in order to allow the material to have increased response to changes in temperature, a desirable property with regards to controlled drug delivery. Thus, the taught process of making the material discloses all of the limitations of instant claims 1-13.

**Claims 14-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gan et al. (*Polymer*, 1997, 38(21), pages 5339-5345) and Lee et al. (*J. Appl. Polymer Sci.*, 1999, 71, pages 221-231) as applied to claim 13 above, and further in view of Liu et al. (*Langmuir*, 1997, 13(24), pages 6421-6426).** Gan et al. in view of Lee et al. teach all of the limitations of instant claims 14-20 (see the above rejection) except for the instantly recited amounts of each of

the ingredients. Gan et al. teaches using from 10 to 21.25 wt% of the methyl methacrylic acid, from 10 to 21.25 wt% of the 2-hydroxyethyl methacrylate, from 20 to 42.5 wt% of the  $\omega$ -methoxy poly(ethylene oxide)<sub>40</sub> undecyl- $\alpha$ -methacrylate, 4 wt% of the ethylene glycol dimethacrylate, and from 15 to 60 wt% of the aqueous component (page 5341, table 1). These ranges overlap some of the instantly recited amounts, and in cases involving overlapping ranges, the courts have consistently held that even a slight overlap in range establishes a *prima facie* case of obviousness. *In re Peterson*, 65 USPQ2d 1379, 1382 (Fed. Cir. 2003). However, the relative amounts instantly recited differ, and not all of the instantly recited values overlap these ranges.

Liu et al. teach transparent nanostructure polymeric materials produced from microemulsions containing  $\omega$ -methoxy poly(ethylene oxide)<sub>40</sub> undecyl- $\alpha$ -methacrylate, methyl methacrylate, 2-hydroxyethyl methacrylate, water, and ethylene glycol dimethylacrylate (abstract, lines 1-5). Liu et al. teaches that the pore size of this material can be regulated by varying the ratios of the 2-hydroxyethyl methacrylate,  $\omega$ -methoxy poly(ethylene oxide)<sub>40</sub> undecyl- $\alpha$ -methacrylate, and water (page 6426, second full paragraph). Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have optimized the amounts of these ingredients, as taught by Liu et al., in order to control the pore size of the polymeric material, which would influence the permeability of the polymeric material to different materials.

### ***Conclusion***

No claims are allowed.



Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Gullede whose telephone number is (571) 270-5756. The examiner can normally be reached on Monday-Thursday 6:00am - 3:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BMG

/Frederick Krass/  
Supervisory Patent Examiner, Art Unit 1612